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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,242	06/23/2006	Yusuke Murakawa	084437-0169	1685

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,242	MURAKAWA ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 10/8/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 102 and 103

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by WO 0243704 (WO '704; US 20040076675 is an English equivalent is maintained) is maintained. The rejection of claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over WO 0243704 (WO '704; US 20040076675 is an English equivalent is maintained).

Applicant argues that WO '704 does not teach a product with improved granulatability or granulatability-improving action of a surfactant, as presently claimed. Applicant cites page 5, lines 13-26 of the instant specification, where improved granulatability is defined and is very different from the improved solubility or oral absorbability of WO '704. Applicant argues that WO '704 aims to improve the solubility or oral absorbability of the slightly water-soluble component, and does not teach or suggest improvement of granulatability. Therefore, one of ordinary skill in the art would not have been motivated to optimize the weight ratio of the compound of WO '704 for the purpose of improving the granulatability.

Applicant's arguments have been fully considered but are not found persuasive. Page 5, lines 13-22 of the instant specification recites "As used in the present specification, the expression "improved granulatability" means having particle sizes and flowability which are suitable for the purpose of reduction of adhesion, scattering or flocculation of the fine powders of the pharmaceutical compound, easy dosing, easy weight, or the like for (granulated) powdered drugs, granules, fine granules, or the like, and further improvement of the compression or fillability for tablets, capsules or the like; or the like, and specifically it can be examined by measuring the particle size distribution, the specific volume and the angle of repose of the granulated product." In the case of WO '704, these granules have "improved granulatability" compared to granules made in a prior reference, in the same meaning of "improved granulatability" defined by the instant specification. Specifically, in the disclosure of WO '704, the granules of the invention are compared to a prior formulation in which aggregation (adhesion) of the granules decreases their solubility and oral absorbability (see paragraph 4). WO '704 has overcome this problem by the disclosed invention, providing increased solubility, oral absorbability, and reduced adhesion (improved granulatability) relative to the prior formulation (see paragraph 9). Thus, WO '704 suggests that the disclosed granules are "suitable for the purpose of reduction of adhesion, scattering or flocculation of the fine powders of the pharmaceutical compound" compared to the prior formulation. That WO '704 uses excipients to accomplish this does not distinguish its granules from that of the instant claims, the latter being open to incorporation of such components. Regarding optimization of the

weight percent of the slightly-water soluble compound, WO '704 discloses a weight ratio of pharmaceutical compound to surfactant of 1:0.1 to 50:.01. As stated in the previous office action, it would be obvious to find the instantly claimed weight ratios of the pharmaceutical compound, as these weight ratios are encompassed by the range of WO '704. See previous office action, pages 5-6. See MPEP § 2144.05, II.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-3, 7-9 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0243704 (hereafter WO '704; US 20040076675 ('675) is an English equivalent and will be referenced hereafter; both documents are already in the record).

WO '704 discloses a pharmaceutical granulated product comprising a slightly water-soluble medicament (a pharmaceutical compound with poor wettability) and a surfactant (see '675: abstract; Examples; Claim 1). The disclosed granulated product provides improved solubility and oral absorbability, which provides an improvement over prior formulations in which particle aggregation (adhesion; granulatability) caused low solubility and oral absorbability (see '675: ¶ 1 and 4). WO '704 discloses an example wherein the weight ratio of Compound (Ia) (a pharmaceutical compound with poor wettability) and sodium lauryl sulfate (a surfactant) is 1:2 (see '675: Example 1). WO '704 discloses 0.3 g pharmaceutical compound per gram of granulated product, which corresponds to 30% pharmaceutical compound by weight (see '675: ¶ 58). WO '704 teaches that the weight percent of the slightly water-soluble component in the composition may range from 0.0001 to 0.5 g per gram of composition, which corresponds to 0.01% to 50% by weight (see '675: ¶ 58). WO '704 specifically discloses an example wherein the weight ratio of Compound (Ia) (a pharmaceutical

compound with poor wettability) and sodium lauryl sulfate (a surfactant) is 1:2. WO '704 further discloses a weight ratio of pharmaceutical compound to surfactant of 1:0.1 to 50:.01 (see '675: ¶ 59). WO '704 discloses molding the granulated product into tablets, which is an embodiment of a molded product as recited in instant claim 9 (see '675: ¶ 68; Examples 28-31).

WO '704 fails to disclose a granulated product wherein at least 35% by weight with respect to the total weight of the product does not pass through a 100-mesh sieve. WO '704 fails to disclose the compound to surfactant ratios of 1: about 0.001 to about 2. WO '704 fails to disclose a compound weight percent range of 40 to 80%.

Instant claim 2 is directed to a granulated product wherein at least 35% by weight with respect to the total weight of the product does not pass through a 100-mesh sieve. The instant specification defines 100-mesh sieve as a sieve having a pore size of 149 microns (see page 7, line 9). Thus, this claim corresponds to a granulated product wherein at least 35% by weight has a pore size of 149 microns or greater.

WO '704 discloses a granulated product wherein 100% by weight with respect to the total weight of the product has a particle size of 420 microns or smaller (see Example 1).

Thus, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to optimize the particle size of WO '704, to increase the bioavailability of the granules, and in this way, arrive at Applicant's range of 149 microns or greater. The rationale for this is that the instant range of 149 microns or greater

overlaps with the range disclosed by WO '704 of 420 microns or smaller. See MPEP § 2144.05, II.

It would have been further obvious to find the instantly claimed compound to surfactant ratio of 1:about 0.001 to about 2, through routine experimentation, to increase the solubility and oral absorbability of the granules, as this range overlaps with the range taught by WO '704 of 1:0.1 to 50:.01.

It would have been further obvious to find the instantly claimed compound weight percent range of 40 to 80%, through routine experimentation, to increase the solubility and oral absorbability of the granules, as this range overlaps with the range taught by WO '704 of 0.01 to 50%.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

January 5, 2009